

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN DAC and )  
PERNIX THERAPEUTICS, LLC, )  
Plaintiffs, )  
v. ) REDACTED - PUBLIC VERSION  
ALVOGEN MALTA OPERATIONS LTD., ) C.A. No. 16-139-WCB  
Defendant. ) [REDACTED]  
[REDACTED]

**ALVOGEN MALTA OPERATIONS LTD.'S MOTION TO STRIKE AND EXCLUDE  
PERNIX'S LATE-DISCLOSED INFRINGEMENT THEORY**

Karen E. Keller (No. 4489)  
David M. Fry (No. 5486)  
Nathan R. Hoeschen (No. 6232)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
kkeller@shawkeller.com  
dfry@shawkeller.com  
nhoeschen@shawkeller.com  
*Attorneys for Defendant*

OF COUNSEL:

Matthew J. Becker  
Chad A. Landmon  
Thomas K. Hedemann  
David K. Ludwig  
AXINN, VELTROP & HARKRIDER LLP  
90 State House Square  
Hartford, CT 06103  
(860) 275-8100

Seth I. Heller  
Christopher M. Gallo  
AXINN, VELTROP & HARKRIDER LLP  
950 F. Street, N.W.  
Washington, DC 20004  
(202) 912-4700

Dated: March 26, 2018

Pursuant to Federal Rule of Civil Procedure 37(b)(2)(A)(ii) and (iii), Defendant Alvogen Malta Operations Ltd. (“Alvogen”) respectfully requests that the Court strike Section IV.C.1. from Pernix Ireland Pain DAC and Pernix Therapeutics, LLC’s (“Pernix”) Opening Brief in Support of Its Motion for Summary Judgment (D.I. 120), and preclude Pernix from asserting its new infringement theory at trial. Pursuant to Local Rule 7.1.1, the parties engaged in a good-faith effort to reach agreement on the matters set forth in this motion, but were unable to reach agreement. Alvogen waives its opening brief, and for its motion states as follows:

**I. Pernix’s New Infringement Theory**

1. In its original infringement contentions, Pernix set forth a single-actor infringement theory for every asserted claim of the ’760 patent. Ex. A (Pernix’s Initial Infringement Contentions) at 1-8.
2. The Court’s claim construction order required Pernix to change course. Claim 1 of the ’760 patent contains the following phrase: “wherein the starting dose is not adjusted relative to a patient without hepatic impairment.” The parties disagreed whether this phrase was a claim limitation (Pernix) or a non-limiting statement of purpose (Alvogen). The Court agreed with Pernix. D.I. 69. The Court also, however, adopted Alvogen’s proposed construction of the term “administering” to mean “delivering into the body” (rather than broadly including, as Pernix proposed, the acts of “prescribing, dispensing, giving or taking”). Id.
3. After the Court issued its claim construction order, Pernix amended its infringement contentions by replacing its single-actor infringement theory with a joint infringement theory for claim 1 of the ’760 patent (and its dependent claims), stating that “[p]hysicians direct and/or control their patients’ administration of a starting dose of Alvogen’s proposed generic product in such a manner as to condition the receipt of treatment on the

patients' administration of the prescribed starting dose. Further, the physician establishes the manner and timing of the patients' administration of the starting dose." Ex. B (Pernix's Amended Infringement Contentions) at 1-2. Consistent with its amended contentions, Pernix's expert only presented a joint infringement theory in his report. Ex. C (Pernix's Opening Infringement Report) at 26 ("all of the elements of claim 1 of the '760 Patent are met . . . because a physician, as instructed by the Alvogen Draft Label, will direct a patient with mild or moderate impairment to take the same starting dose"); id. at 32 ("all of the elements of claim 1 of the '760 Patent are met when physicians direct patients with mild or moderate hepatic impairment to self-administer Alvogen's Proposed ANDA Product according to the physician's instructions").

4. Contrary to its prior position, Pernix in its summary judgment motion now reasserts a single-actor infringement theory and argues that "[j]oint infringement . . . is not required for '760 patent claims 1-4 and 11." Id.

5. Pernix repeatedly characterizes joint infringement as "Alvogen's 'joint infringement' defense." *See, e.g.*, D.I. 120 at 12 n.4. But joint infringement is *Pernix's* asserted infringement theory in this case for claims 1-4 and 11 of the '760 patent. Indeed, its infringement expert specifically alleged that "the physician and patient jointly practice the claimed method" (Ex. C at 28), and that is also Pernix's sole allegation in its amended infringement contentions.

## **II. Pernix's New Theory Should Be Excluded**

6. When a party fails to comply with its discovery obligations, courts in the Third Circuit apply a series of factors (the "Pennypack factors") to determine whether the untimely theories should be excluded. St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec.

Indus. Co., C.A. No. 04-1436-LPS, 2012 U.S. Dist. LEXIS 40103, at \*11-12 (D. Del. Mar. 26, 2012). The Pennypack factors include:

(1) the importance of the information withheld, (2) the prejudice or surprise to the party against whom the evidence is offered, (3) the likelihood of disruption of the trial, (4) the possibility of curing the prejudice, (5) the explanation for the failure to disclose, and (6) the presence of bad faith or willfulness in not disclosing the evidence.

Id. “The determination of whether to exclude evidence or defenses is committed to the discretion of the Court.” Id.

7. Taken together, the Pennypack factors weigh strongly in favor of excluding Pernix’s new infringement theory.

#### **A. Importance of the Information Withheld**

8. Alvogen is not asking the Court to strike Pernix’s infringement case in its entirety. Indeed, this motion is directed to a single infringement theory for a single subset of claims in one asserted patent. Furthermore, Pernix will be free to proceed on its timely disclosed theories. This factor therefore weighs in favor of exclusion. And regardless of the importance of this new theory to Pernix’s infringement case, this factor would not weigh against exclusion because the “situation is of [Pernix’s] own making.” AVM Techs., LLC v. Intel Corp., C.A. No. 10-610-RGA, 2013 U.S. Dist. LEXIS 66604, at \*5 (D. Del. Mar. 29, 2013) (granting motion to exclude a late-disclosed damages theory, even where the exclusion would “leave [the plaintiff] without evidence of damages”); see also St. Clair, 2012 U.S. Dist. LEXIS 40103, at \*21-23 (recognizing that the plaintiff’s new theories were “extremely important to its case,” but finding that “this factor is neutral” because the plaintiff “violated the Scheduling Orders when it failed to raise all of its infringement contentions at the appropriate time”).

**B. Prejudice to Alvogen**

9. The prejudice to Alvogen is both significant and incurable. The purpose of contentions is to provide the other side with notice of a party's legal theories and an opportunity to test those theories in discovery. If Pernix had disclosed its single-actor infringement theory in its amended contentions (or even in its opening expert report), it would have shaped Alvogen's approach to the deposition of Pernix's infringement expert and sparked new questions, and it would have given Alvogen the opportunity to respond to this theory in its rebuttal report on non-infringement. Even if Alvogen were permitted to take curative discovery and supplement its non-infringement report now, this factor would still weigh strongly in favor of exclusion. See St. Clair, 2012 U.S. Dist. LEXIS 40103, at \*23 (finding "that the Defendants will likely suffer prejudice if St. Clair is allowed to supplement its expert reports because Defendants will have to spend additional time and money to refute St. Clair's new theories").

**C. Likelihood of Disrupting Trial**

10. Trial is less than three months away, and Alvogen has been working under the assumption that it would be addressing a joint infringement theory—i.e., the only theory that Pernix timely disclosed for claims 1-4 and 11 of the '760 patent. It will take a significant amount of time for Alvogen to revamp its trial strategy and presentation if Pernix is allowed to assert a new theory that was never considered or vetted in expert discovery. See id. at \*24 (finding that this factor disfavored supplementation where the impacted "cases will suffer further delay and prolonged disruption").

**D. Whether Prejudice Can Be Cured**

11. While "the prejudice [Alvogen] will suffer can be partially cured by allowing [Alvogen] to file rebuttal expert reports and, if warranted, new motions for summary judgment,

... the prejudice [Alvogen] face[s] cannot be wholly cured.” Id. at \*24-25. The delay and additional expense caused by Pernix’s late disclosure of its new infringement theory are inevitable, even if the Court allows the parties to reopen fact and expert discovery on Pernix’s new theory. Moreover, it would be fundamentally unfair to impose this burden on Alvogen simply because Pernix decided to change its infringement theory at the last minute.

#### **E. Pernix Has No Excuse for Failing to Timely Disclose Its Theories**

12. Pernix has no excuse for its late disclosure. Pernix previously asserted a single-actor infringement theory, and then made the deliberate decision to drop that theory after claim construction. At no point after serving its amended contentions did Pernix seek leave to amend its contentions or its expert reports, and its motion for summary judgment does not even acknowledge—let alone attempt to explain—this change in course. See id. at \*25 (finding that “this factor disfavors permitting supplementation” when the delinquent party “fails to present a valid explanation for its failure to disclose its infringement contentions and supporting expert reports in accordance with the deadline set by the Scheduling Orders”). Indeed, if this case had stayed on its original trial schedule, Pernix would not have been able to raise this theory *at all* until its infringement expert was on the witness stand—at which point it almost certainly would have been excluded as coming too late.

#### **F. Bad Faith or Willfulness**

13. Alvogen does not pretend to know Pernix’s motives. But even where there is no evidence of bad faith or willfulness, a strong showing on the other Pennypack factors will support exclusion. See id. at \*25-26 (noting that “Defendants have made no allegation of bad faith or willfulness and there is no evidence of any such conduct[,]” but concluding that “the Pennypack factors indicate that St. Clair should not be granted leave to amend its expert reports

and file new infringement contentions"). Pernix should not be rewarded for its decision to wait until the last minute to reassert a single-actor infringement theory, after it is too late for Alvogen to meaningfully respond.

\* \* \*

14. In short, the Pennypack factors weigh strongly in favor of excluding Pernix's single-actor infringement theory with respect to claims 1-4 and 11 of the '760 patent. "To allow these new expert opinions, in the middle of summary judgment briefing and just prior to trial, would unduly prejudice [Alvogen]" and run contrary to the purpose of the disclosure requirements of the federal rules. INVISTA N. Am. S.à.r.l., C.A. No. 11-1007-SLR-CJB, 2013 U.S. Dist. LEXIS 88633, at \*11-12 (D. Del. June 25, 2013).

WHEREFORE, Alvogen respectfully requests that the Court enter the enclosed order striking Section IV.C.1. from Pernix's Opening Brief in Support of Its Motion for Summary Judgment (D.I. 120), and precluding Pernix from asserting its new infringement theory at trial.

Respectfully submitted,

SHAW KELLER LLP

/s/ David M. Fry

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Karen E. Keller (No. 4489)  
David M. Fry (No. 5486)  
Nathan R. Hoeschen (No. 6232)  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
kkeller@shawkeller.com  
dfry@shawkeller.com  
nhoeschen@shawkeller.com  
*Attorneys for Defendant*

OF COUNSEL:

Matthew J. Becker  
Chad A. Landmon  
Thomas K. Hedemann  
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90 State House Square  
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(860) 275-8100

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Christopher M. Gallo  
AXINN, VELTROP & HARKRIDER LLP  
950 F. Street, N.W.  
Washington, DC 20004  
(202) 912-4700

Dated: March 26, 2018

**CERTIFICATE OF SERVICE**

I, David M. Fry, hereby certify that on March 26, 2018, this document was served on the persons listed below in the manner indicated:

**BY EMAIL**

Michael P. Kelly  
Daniel M. Silver  
Benjamin A. Smyth  
MCCARTER & ENGLISH LLP  
Renaissance Centre  
405 N. King St., 8th Floor  
Wilmington, DE 19801  
(302) 984-6331  
mkelly@mccarter.com  
dsilver@mccarter.com  
bsmyth@mccarter.com

Dominick A. Conde  
Christopher P. Borello  
Brendan M. O'Malley  
David G. Varghese  
John Calabro  
Steven C. Kline  
FITZPATRICK, CELLA, HARPER & SCINTO  
1290 Avenue of the Americas  
New York, NY 10104  
(212) 218-2371  
dconde@fchs.com  
cborello@fchs.com  
bomalley@fchs.com  
jcalabro@fchs.com  
dvarghese@fchs.com  
skline@fchs.com

*/s/ David M. Fry*

---

Karen E. Keller (No. 4489)  
Jeffrey T. Castellano (No. 4837)  
David M. Fry (No. 5486)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
kkeller@shawkeller.com  
jcastellano@shawkeller.com  
dfry@shawkeller.com  
*Attorneys for Defendant*

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ALVOGEN MALTA OPERATIONS LTD., )  
Defendant. )

**[PROPOSED] ORDER**

This \_\_\_\_ day of \_\_\_\_\_, 2018, having considered Defendant Alvogen Malta Operations Ltd.’s (“Alvogen”) Motion to Strike and Exclude Pernix Ireland Pain DAC and Pernix Therapeutics, LLC’s (“Pernix”) Late-Disclosed Infringement Theory, IT IS HEREBY ORDERED that the motion is GRANTED.

The Court hereby strikes Section IV.C.1. from Pernix’s Opening Brief in Support of Its Motion for Summary Judgment (D.I. 120), and precludes Pernix from asserting its late-disclosed infringement theory at trial.

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WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE

# **Exhibit A**

**REDACTED**

# **Exhibit B**

**REDACTED**

# **Exhibit C**

**REDACTED**